

Exhibit 9

EXPERT REPORT

**Analysis of Distributor and Manufacturer
Regulatory Compliance to Maintain
Effective Controls for the Prevention of
Diversion of Controlled Substances**

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determine for which orders there was any²³⁹ due diligence investigation (or review) conducted and documented prior to shipping any further products of this same drug family. Cardinal had repeatedly failed to conduct and document adequate due diligence to dispel the suspicious activity prior to shipping additional opioids of the same drug family. The chart contained in Schedule III shows that Cardinal Health continued to ship the same opioid drugs to customers who Cardinal Health had already determined were placing suspicious orders in CT1 [REDACTED] of the time ([REDACTED] orders), and of those orders, [REDACTED] ([REDACTED] orders) were shipped with no documented due diligence

3. Cardinal Health failed to report suspicious orders of controlled substances in violation of the reporting requirement set forth in 21 C.F.R. § 1301.74(b).

Cardinal Health timely reported zero suspicious orders in CT1 jurisdictions (Summit and Cuyahoga Counties, Ohio) from 1996 to at least 2008, based on the records provided. The ILR is an after-the-fact distribution report which is insufficient. Cardinal has not been able to produce suspicious orders that were reported to the DEA for CT1 during Policy Period #2 (2008-2012). However, it was Cardinal Health's practice not to report suspicious orders but to "report an order as suspicious when the customer appeared suspicious" and Cardinal Health was going to terminate service to that customer.²⁴⁰ Waiting to the point of termination of a customer prior to reporting any suspicious orders related to the customer is not sufficient to meet the reporting requirement. This conclusion is supported by several documents produced by Cardinal Health. First, Cardinal's November 1, 2012 Audit Committee Meeting packet indicates that during fiscal years 2010 and 2011 Cardinal only reported [REDACTED] suspicious orders, respectively, nationwide. This is in stark contrast to the [REDACTED] increase of reported suspicious orders that allegedly occurred in 2012, according to the document.²⁴¹ Additionally, during this same period of time the Baltimore DEA office provided a presentation to Cardinal Health that, among other things, outlined that between 2008 and October 1, 2011, Cardinal did not report any suspicious orders of oxycodone products in Maryland.²⁴²

Finally, during Policy Period #3 Cardinal Health reported [REDACTED] suspicious order but continued to ship the same base codes to many of those customers.²⁴³ Any additional orders from these customers without having been cleared would also constitute a suspicious order and should have been reported to the DEA as such. Also during the 2012-2015 timeframe, Cardinal's employee testified that Cardinal failed to report to the DEA approximately 14,000 separate suspicious orders from around the country. According to Mr. Cameron these were for "subbase

²³⁹ Whether the due diligence was sufficient or not is an additional consideration.

²⁴⁰ See *Investigation Report of the Special Demand Committee*, CAH_MDL_PRIORPROD_HOUSE_0003331 at page 36; also see *Supplemental Declaration of Michael A. Mone*, CAH_MDL_PRIORPROD_DEA12_00014762 at page 8; also see CAH_MDL2804_3262274, 03262438.

²⁴¹ CAH_MDL2804_03262274, 03262438.

²⁴² CAH_MDL2804_02509732, 02509741.

²⁴³ See "Know Your Customer" section above.

codes” which would generally be for more highly abused dosages.²⁴⁴ Additionally, using any of the below methodologies, as described in the Expert Report of Craig McCann, it is apparent Cardinal Health failed to report thousands of suspicious orders arising out Cuyahoga County and Summit County.²⁴⁵

4. Cardinal Health failed to stop shipment of suspicious orders of controlled substances in violation of the requirement to maintain effective controls against diversion as set forth in 21 U.S.C.A. § 823(b)(1) [1970].

Again, the premise of the CSA is to ensure that when dealing with these controlled substances that are highly addictive in nature and dangerous that we do so in a way that best protects our communities. This is signified in the CSA’s requirement to all registrants’ to “maintain effective controls” against diversion. With this understanding, even if Cardinal Health had properly identified suspicious orders, its corporate policy from 1996 to 2008 was to ship anyway. This is a blatant failure to maintain effective controls to prevent diversion and a breach of their regulatory obligations as a registrant.

Being that I have not specifically seen any suspicious orders identified by Cardinal Health as being reported for customers in Cuyahoga and Summit Counties during Policy Period #2, I cannot say whether Cardinal Health shipped any orders into Cuyahoga and/or Summit Counties that Cardinal Health identified as suspicious. However, I can say that Cardinal Health during this timeframe did ship suspicious orders that should have been identified.²⁴⁶

During Policy Period #3 it appears as Cardinal Health did halt shipment of the orders which it identified as suspicious. However, it is my opinion based on what has been provided and set out in Schedule III that Cardinal Health continued to ship base code 9143 and 9193 to the same registrant after reporting a suspicious order. Such conduct would constitute a violation of Cardinal Health’s duty to maintain effective controls against diversion.

B. McKesson Corporation

McKesson Corporation

Distribution Center: New Castle, Pennsylvania

DEA Registrant Number: [REDACTED]

Transactional Data Disclosed: Date Range: 10/01/04 – 6/30/2018²⁴⁷

²⁴⁴ Depo. of Todd Cameron, pp. 268-271.

²⁴⁵ See Section III, “Identifying Suspicious Orders Distributed in CT1.”

²⁴⁶ See Section III.(A.)(2.) above.

²⁴⁷ MCKMDL00579972; MCKMDL00478913; MCKMDL00409045; MCKMDL00606062.

Cuyahoga ²⁴⁸	Total Dosage	MME	Base Weight
Oxycodone			
Hydrocodone			

Summit ²⁴⁹	Total Dosage	MME	Base Weight
Oxycodone			
Hydrocodone			

1. Court Ordered SOMS Discovery Disclosures:

- *McKesson Corporation's Objections and Responses to Plaintiffs' Combined Discovery Requests (07/31/2018);*
- *McKesson Corporation's Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests (11/30/2018);*
- *McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests (03/04/2019).*
- *McKesson Corporation's Third Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests (3/29/2019).*

2. SOMS Corporate Policy Disclosed:

*McKesson Drug Operations Manual – Section 55 (January 15, 1997)*²⁵⁰

McKesson Corporation (hereinafter “McKesson”) utilized this system from at least 1997 to May 2007. Section 55 outlines five different reports concerning a customer’s purchases (Controlled Substances Sales Report, Controlled Substances Customer Purchase Report, Daily Controlled Substance Suspicious Order Warning Report, Monthly Controlled Substance Suspicious Purchases Report and the Monthly ARCOS Customer Recap Variance). (MCKMDL00651873 at 00651919-20). However, the output from these reports was rather basic. McKesson created daily and monthly reports that documented retrospective sales of controlled substances, including opioids, when those sales exceeded three times of that customer’s 12 month purchase average for that base code. (MCKMDL00651873 at 00651919-20; 1/10/19 Gary Hilliard Depo. at 163:21-169:7). After it was generated, a hard copy of the report was mailed or faxed to the local DEA office. The reports that were generated were known as DU-45 reports. However,

²⁴⁸ See Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 136.

²⁴⁹ See Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 766.

²⁵⁰ MCKMDL00651873.